

fulfilled this requirement to date. All others require substantial modification of conditions and/or are rendered ineffective by components of cell culture supernatants.

[0109] References:

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SUMMARY OF THE INVENTION

[0110] In a first aspect, the present invention is directed to a method for purification of a hydrated target species of biological origin in a sample, comprising contacting the sample with a hydrated surface of an undissolved material and a constraining agent in an amount sufficient to retain more than 50% of the hydrated target species at the hydrated surface of the

undissolved material, wherein (i) the undissolved material comprises particles; and (ii) the constraining agent is an aqueous soluble uncharged linear or branched non-ionic organic polymer. Methods and compositions and kits adapted for performing the invention are also described herein. In certain examples, the disclosure provides a method for purification of a target species of biological origin in a sample including the steps of (i) contacting the sample with the hydrated surface of an

undissolved material and (ii) contacting the sample and undissolved material with a preferentially excluded agent in an amount sufficient to cause at least a fraction of the now preferentially hydrated target species to be retained at the now preferentially hydrated surface of the undissolved material. This form of association is herein also referred to as constrained cohydration; the preferentially excluded agent is sometimes referred to as the constraining agent; and for brevity, preferentially hydrated molecules and surfaces are referred to simply as “hydrated.” In certain such examples, more than 50% of the hydrated target species is retained at the hydrated surface of the undissolved material by the constraining agent and in some examples substantially all of the target species is retained. In certain such examples, at least one individual of the hydrated target species is retained at the hydrated surface exclusively by constrained co-hydration caused by the presence of the constraining agent. In certain such examples under such conditions substantially all of the target species is retained at the hydrated surface exclusively by constrained co-hydration caused by the presence of the constraining agent. In certain such examples, the exclusive retention of the hydrated target species at the hydrated surface by constrained co-hydration due to the presence of the constraining agent can be demonstrated by termination of such retention through the removal or reduction of the concentration of the constraining agent.

[0111] In certain examples described herein, methods and associated compositions and kits are provided for practice of the examples in the context of a tripartite system separation, precipitation method, fluidized bed process or a convective chromatographic process.

BRIEF DESCRIPTION OF THE DRAWINGS

[0112] **Figure 1** shows the relationship between the percentage of IgM retained by constrained co-hydration at the surface of a hydrated monolith and pH for different percentages of the preferentially excluded agent, PEG-6000 (8%, 9%, 10%, 11%, and 12%) as described in Example 5.

[0113] **Figure 2** shows the relationship between the percentage of IgM retained by constrained co-hydration at the surface of a hydrated monolith and concentration of NaCl for different percentages of the preferentially excluded agent, PEG-6000 (8%, 9%, 10%) as described in Example 6.

[0114] **Figure 3** shows the relationship between the percentage of IgM retained by constrained co-hydration at the surface of a hydrated monolith and percentages of a preferentially excluded agent, PEG of varying molecular weights (6000, 4000, and 2000) as described in Example 7.

CLAIMS

1. A method for purification of a hydrated target species of biological origin in a sample, comprising:
contacting the sample with a hydrated surface of an undissolved material and a constraining agent in an amount sufficient to retain more than 50% of the hydrated target species at the hydrated surface of the undissolved material, wherein
 - (i) the undissolved material comprises particles; and
 - (ii) the constraining agent is an aqueous soluble uncharged linear or branched non-ionic organic polymer.
2. The method of claim 1, wherein the constraining agent is selected from the group consisting of polyethylene glycol, polypropylene glycol, and polyvinyl-pyrrolidone.
3. The method of claim 2, wherein the constraining agent comprises polyethylene glycol having an average polymer weight between 100 and 10000 Da.
4. The method of any one of claims 1 to 3, wherein the particles comprise synthetic particles.
5. The method of any one of claims 1 to 4, wherein the size of the particles is between 100 nm and 500 μm .
6. The method of any one of claims 4 to 5, wherein the synthetic particles comprise porous particles.
7. The method of any one of claims 4 to 6, wherein the synthetic particles comprise non-porous particles.
8. The method of any one of claims 4 to 7, wherein the synthetic particles comprise silica particles.
9. The method of any one of claims 1 to 8, wherein the particles comprise nanoparticles or microparticles.

10. The method of any one of claims 4 to 9, wherein the synthetic particles comprise magnetic particles, paramagnetic particles or high-density particles.
11. The method of any one of claims 4 to 10, wherein the synthetic particles comprise metal-core particles having a polymer coating or metal core particles having a cellulose coating.
12. The method of any one of claims 1 to 11, wherein the particles are porous or non-porous particles packed in a chromatography column.
13. The method of any one of claims 1 to 12, wherein the target species is an antibody.
14. The method of claim 13, wherein the antibody is a polyclonal or monoclonal antibody of the class IgA, IgD, IgE, IgG, or IgM, or a fragment thereof, or wherein the fragment is selected from a Fab, F(ab')₂, Fv, scFv, Fd, dAb, and Fc fragments.
15. The method of any one of claims 1 to 12, wherein the target species is a virus, lipid enveloped virus, protein capsid virus or virus like particle.
16. The method of any one of claims 1 to 15, wherein the particles comprise one or more polar chemical moieties.
17. The method of any one of claims 1 to 16, wherein the particles are hydroxylated, glycosylated, or polyhydroxylated.
18. The method of any one of claims 9 to 17, wherein the particles comprise starch.
19. The method of any one of claims 1 to 18, wherein the particles comprise allantoin.
20. The method of any one of claims 1 to 19, wherein the target species is retained exclusively by constrained cohydration under conditions of pH or conductivity that discourage direct chemical interactions between the hydrated target species and the particles.